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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA
SOUTHERN DIVISION**

Ashely Garcia individually and on behalf of her
minor child A.V.

Plaintiff,

v.

Beech-Nut Nutrition Company and Gerber
Products Company
Defendants.

COMPLAINT FOR DAMAGES

DEMAND FOR JURY TRIAL

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INTRODUCTION

1. This case involves a group of manufacturers/sellers—namely, Beech-Nut Nutrition Company and Gerber Products Company (“Defendants”)—that *knowingly* sold baby food products (“Baby Foods”) which contain dangerous levels of toxic heavy metals—lead, arsenic, and mercury (collectively “Toxic Heavy Metals”), which are known to be severe neurotoxins—and how such toxic exposures substantially contributed to Plaintiff developing lifelong brain injury. Plaintiff is a child who lives with debilitating brain injury, namely in the form of the neurodevelopmental disorder autism spectrum disorder (“ASD”) and related *sequelae* because, as an infant, he consumed poisonous Baby Foods manufactured and/or sold by these Defendants. This case seeks to hold the Defendants accountable for their reprehensible conduct and ensure they are punished for permanently affecting Plaintiff’s ability to live a fulfilling life.

2. That Defendants’ Baby Foods are laced with staggering amounts of Toxic Heavy Metals recently made headlines following research and a Congressional investigation. In February 2021, the U.S. House of Representatives’ Subcommittee on Economic and Consumer Policy, Committee on Oversight and Reform released a report containing shocking details of Defendants’ tainted Baby Foods based on the submission of internal test results and company documents. Specifically, the Subcommittee found that Defendants sell Baby Foods containing levels of heavy metals ranging from tens to hundreds of parts per billion (“ppb”),¹ far eclipsing domestic and international regulatory standards. With a chilling note the Subcommittee concluded that “[m]anufacturers *knowingly* sell these products to unsuspecting parents, in spite of internal company standards and test results, and without any warning labeling whatsoever.”² (emphasis added). Indeed,

¹ Ppb (or ppbm) is used to measure the concentration of a contaminant in soils, sediments, and water. 1 ppb equals 1 µg (microgram) of substance per kg of solid (µg/kg). For the average baby weighing approximately 3kg, the quantities of Toxic Heavy Metals found in Defendants’ Baby Foods, as explained below, pose significant health risks.

² Ex. 1, Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight and Reform U.S. House of Representatives, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021) (“Subcommittee Report”) at 59, available at: <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2021-02-04%20ECP%20Baby%20Food%20Staff%20Report.pdf>.

1 following the Congressional findings and subsequent public uproar, Defendant Beech-Nut recalled
 2 one of its baby food product lines from the market, citing dangerous levels of arsenic in its single
 3 grain rice cereal, and exited the rice cereal market altogether.³

4 3. The high levels of Toxic Heavy Metals found in Defendants' Baby Foods are, in part,
 5 a function of the ingredients used by Defendants to manufacture their Baby Foods, the setting of
 6 dangerously inflated internal limits which Defendants willingly flouted, disregard of regulatory
 7 standards, and corporate policies which failed to test finished products before market distribution,
 8 purchase by unknowing parents, and consumption by vulnerable infants.

9 4. Defendants' malicious recklessness and callous disregard for human life has wreaked
 10 havoc on the health of countless vulnerable children, all so that Defendants could maximize profits
 11 while deliberately misleading parents regarding the safety of their Baby Foods. Accordingly, this
 12 lawsuit will not only ensure that Plaintiff is duly compensated for his tragic injuries and Defendants
 13 punished, but that future generations are protected from the poisonous products that Defendants
 14 pander as "food".

15 **PARTIES**

16 **I. Plaintiff**

17 5. Plaintiff, A.V. is a minor child and citizen of Nevada and no other state.

18 6. Ashely Garcia is the mother of Plaintiff, A.V.

19 7. Ashely Garcia brings this suit individually, to the extent she is permitted to recover
 20 damages for costs incurred for the treatment of A.V.'s autism, and on behalf of her minor child A.V.

21 8. At all relevant times, the baby food products purchased by Ashely Garcia and ingested
 22 by her minor child, A.V., were purchased and ingested within the State of Nevada.

23 **II. Defendants**

24 9. Defendant Beech-Nut Nutrition Company ("Beech-Nut") is a citizen of Delaware and
 25

26 ³ FDA, *Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single*
 27 *Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment*, available at:
 28 <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beech-nut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and>

1 New York with its principal place of business located at 1 Nutritious Pl., Amsterdam, NY 12010.
2 Beech-Nut sells Baby Foods under the brand name Beech-Nut. Beech-Nut produces Baby Foods
3 aimed at infants 4+ months up to 12+ months and includes a variety of cereals, “jars”, and “pouches”
4 for these age groups. At all relevant times, Beech-Nut has conducted business and derived substantial
5 revenue from its manufacturing, advertising, distributing, selling, and marketing of Baby Foods
6 within this judicial district.

7 10. Defendant Gerber Products Company (“Gerber”) is a citizen of Michigan with its
8 principal place of business located at 445 State Street, Fremont, MI 49413-0001. Gerber sells Baby
9 Foods under the brand name Gerber. Gerber organizes its products into broad categories of
10 “formula”, “baby cereal”, “baby food”, “snacks”, “meals & sides” “beverages” and “organic”. At all
11 relevant times, Gerber has conducted business and derived substantial revenue from its
12 manufacturing, advertising, distributing, selling, and marketing of Baby Foods within this judicial
13 district.

14 11. The true names and/or capacities, whether individual, corporate, partnership,
15 associate, governmental, or otherwise, of Defendants DOES 1 through 100, inclusive, and each of
16 them, are unknown to Plaintiff at this time, who therefore sue said Defendants by such fictitious
17 names. Plaintiff is informed and believe, and thereon allege, that each Defendant designated herein
18 as a DOE caused injuries and damages proximately thereby to Plaintiff as hereinafter alleged; and
19 that each DOE Defendant is liable to the Plaintiff for the acts and omissions alleged herein below,
20 and the resulting injuries to Plaintiff, and damages sustained by Plaintiff. Plaintiff will amend this
21 Complaint to allege the true names and capacities of said DOE Defendants when that same is
22 ascertained. At all relevant times, Defendants and DOES 1 through 100, inclusive, and each of them,
23 expected or should have expected that their acts would have consequences within the United States of
24 America including the State of California and including Los Angeles County, said Defendants
25 derived and derive substantial revenue therefrom.

26 **JURISDICTION AND VENUE**

27 12. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is
28 complete diversity of citizenship between the parties. In addition, Plaintiff seeks damages in excess

1 of \$75,000, exclusive of interest and costs.

2 13. This Court has personal jurisdiction over Defendants insofar as Defendants are
3 authorized and licensed to conduct business in the State of Nevada, maintain and carry on systematic
4 and continuous contacts in this judicial district, regularly transact business within this judicial district,
5 and regularly avail themselves of the benefits of this judicial district.

6 14. Additionally, Defendants caused tortious injury by acts and omissions in this judicial
7 district and caused tortious injury in this district by acts and omissions outside this district while
8 regularly doing and soliciting business, engaging in a persistent course of conduct, and deriving
9 substantial revenue from goods used or consumed and services rendered in this judicial district.

10 15. Venue is proper before this Court pursuant to 28 U.S.C. § 1391 because a substantial
11 part of the events or omissions giving rise to the claim occurred in this judicial district.

12 **FACTUAL ALLEGATIONS**

13 **I. Rising Concerns Regarding the Presence of Toxic Heavy Metals in Baby Foods**

14 16. In October 2019, an alliance of nonprofit organizations, scientists and donors named
15 “Happy Babies Bright Futures” (“HBBF”), dedicated to designing and implementing “outcomes-
16 based programs to measurably reduce babies’ exposures to toxic chemicals”⁴, published a report
17 investigating the presence of Toxic Heavy Metals in baby foods.⁵ The HBBF Report tested 168
18 different baby foods sold on the U.S. market and concluded that “[n]inety-five percent of baby foods
19 tested were contaminated with one or more of four toxic heavy metals—arsenic, lead, cadmium and
20 mercury. All but nine of 168 baby foods contained at least one metal; most contained more than
21 one.”⁶ Specifically, the HBBF report identified “puffs and other snacks made with rice flour”,
22 “[t]eething biscuits and rice rusks”, “infant rice cereal”, “apple, pear, grape and other fruit juices”,
23 and “carrots and sweet potatoes” manufactured by the Defendant Baby Food Companies as

24 ⁴ <https://www.hbbf.org/solutions>.

25 ⁵ Healthy Babies Bright Futures, *What’s in My Baby’s Food? A National Investigation Finds 95*
26 *Percent of Baby Foods Tested Contain Toxic Chemicals That Lower Babies’ IQ, Including Arsenic*
27 *and Lead* (Oct. 2019) (“HBBF Report”), available at:
28 www.healthybabyfood.org/sites/healthybabyfoods.org/files/2019-10/BabyFoodReport_FULLREPORT_ENGLISH_R5b.pdf).

⁶ *Id.* at 6.

1 particularly high in Toxic Heavy Metals.⁷

2 17. The results of the HBBF report were consistent with that of the U.S. Food and Drug
3 Administration (“FDA”) which had, in 2017, detected one or more of the four Toxic Heavy Metals in
4 33 of 39 types of baby food tested.⁸ However, the HBBF reported that “[f]or 88 percent of baby foods
5 tested by HBBF—148 of 168 baby foods—FDA has failed to set enforceable limits or issue guidance
6 on maximum safe amounts.”⁹ The HBBF’s findings were by no means an outlier. Eight months
7 prior to publication of the HBBF report, a study conducted by scientists at the University of Miami
8 and the Clean Label Project “examined lead...concentrations in a large convenience sample of US
9 baby foods.”¹⁰ The study detected lead in 37% of samples.¹¹ This was consistent with findings by
10 researchers examining baby food products in other parts of the world.

11 **II. Congressional Investigation Finds Substantial Presence of Heavy Metals in Baby Foods** 12 **Sparking National Outrage**

13 18. On February 4, 2021, the U.S. House of Representatives’ Subcommittee on Economic
14 and Consumer Policy, Committee on Oversight and Reform, published a report detailing its findings
15 that Toxic Heavy Metals—including lead, arsenic, and mercury—were present in “significant levels”
16 in numerous commercial baby food products.¹² Four companies—Hain, Gerber, Nurture, and Beech-
17 Nut—produced internal testing policies, test results for ingredients and finished products, and
18 documentation about what the companies did with ingredients and/or finished products that exceeded
19 their internal testing limits. Three companies—Plum, Walmart, and Sprout—refused to cooperate.¹³

20 19. The Subcommittee reported that the data submitted by the companies unequivocally
21 revealed that a substantial number of Defendants’ finished products and/or ingredients used to
22

23 ⁷ *Id.* at 10-11

24 ⁸ *Id.* at 6.

25 ⁹ *Id.* at 6.

26 ¹⁰ Gardener, et al., *Lead and cadmium contamination in a large sample of United States infant*
27 *formulas and baby foods*, 651 SCI. TOTAL ENVIRON. 1, 822-827 (2019), available at:
<https://www.sciencedirect.com/science/article/abs/pii/S0048969718334442?via%3Dihub>.

27 ¹¹ *Id.*

28 ¹² *See generally* Subcommittee Rpt.

¹³ Subcommittee Rpt. at 2.

1 manufacture the Baby Foods are tainted with significant levels of Toxic Heavy Metals, namely lead,
 2 arsenic, and mercury.¹⁴ And, where the Defendants did set internal limits for the amount of metals
 3 they allowed in their foods, Defendants routinely flouted their own limits and sold foods that
 4 consistently tested above their limits.

5 20. **Beech-Nut.** Beech-Nut used ingredients after they tested as high as 913.4 ppb arsenic.
 6 Beech-Nut routinely used high-arsenic additives that tested over 300 ppb arsenic to address product
 7 characteristics such as “crumb softness.” On June 8, 2021, four months following the Congressional
 8 findings, Beech-Nut issued a voluntary recall of its infant single grain rice cereal and exited the rice
 9 cereal market completely.¹⁵ In its recall, Beech-Nut confirmed that its products exceed regulatory
 10 arsenic limits.¹⁶ And, Beech-Nut used ingredients containing as much as 886.9 ppb lead, as well as
 11 483 products that contained over 5 ppb lead, 89 that contained over 15 ppb lead, and 57 that
 12 contained over 20 ppb lead. In a follow-up report in September 2021 focused on Defendants Beech-
 13 Nut and Gerber’s infant rice cereals, Congress noted that Beech-Nut rice cereal tested up to 125 ppb
 14 inorganic arsenic and averaged 85.47 ppb inorganic arsenic.¹⁷ Beech-Nut’s practice of testing
 15 ingredients, rather than finished products, for toxic heavy metals appears to have contributed to its
 16 failure to detect the dangerous inorganic arsenic levels in its recalled products. Lastly, Beech-Nut
 17 does not even test for mercury in baby food.

18 21. **Gerber** used high-arsenic ingredients, using 67 batches of rice flour that had tested
 19 over 90 ppb inorganic arsenic. Gerber used ingredients that tested as high as 48 ppb lead; and used
 20 many ingredients containing over 20 ppb lead. Gerber rarely tests for mercury in its baby foods. In
 21

22 ¹⁴ *Id.* at 2-3.

23 ¹⁵ FDA, *Beech-Nut Nutrition Company Issues a Voluntary Recall of One Lot of Beech-Nut Single*
 24 *Grain Rice Cereal and Also Decides to Exit the Rice Cereal Segment*, available at:

24 <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/beech-nut-nutrition-company-issues-voluntary-recall-one-lot-beech-nut-single-grain-rice-cereal-and>

25 ¹⁶ *Beech-Nut to stop selling baby rice cereal after finding high arsenic levels* (CNN, June 9, 2021),
 26 available at:

26 <https://www.cnn.com/2021/06/09/health/beech-nut-baby-food-recall-wellness/index.html>.

27 ¹⁷ Ex. 2, Staff Report, Subcommittee on Economic and Consumer Policy Committee on Oversight
 28 and Reform U.S. House of Representatives, *New Disclosures Show Dangerous Levels of Toxic Heavy Metals in Even More Baby Foods* (September 29, 2021) (“Second Congress Report”).

the September 2021 follow-up Congressional report, it was revealed that Gerber’s rice cereal tested up to 116 ppb inorganic arsenic, and its average rice cereal product contained 87.43 ppb inorganic arsenic, which is even higher than the amount contained in Beech-Nut’s average rice cereal product. While Beech-Nut recalled some of its products and completely discontinued sales of its rice cereal, Gerber has taken no such actions to protect children.

22. The metal concentrations discussed above and further below greatly surpass the limits allowed by U.S. regulatory agencies. There are no FDA regulations governing the presence of Toxic Heavy Metals in the majority of Baby Foods with the exception of 100 ppb inorganic arsenic in infant rice cereal and proposed (not yet final) limits for lead in certain baby food categories. To the extent such regulations exist, the quantities of Toxic Heavy Metals in Defendants’ Baby Foods far exceed any permissible FDA levels. To be sure, the FDA has set the maximum contaminant levels (“MCL”) in bottled water at 10 ppb inorganic arsenic, 5 ppb lead, and the EPA has capped the allowable level of mercury in drinking water at 2 ppb. However, these limits were created in reference to *adult* exposure, not infants. Compared to these thresholds, the test results of the Defendants’ Baby Foods and their ingredients are multiple folds greater than the permitted metal levels.

23. Moreover, compounding these troubling findings, the Defendants set internal limits for the presence of Toxic Heavy Metals in their foods that were, themselves, dangerously high and then routinely failed to abide by those inadequate standards, as discussed below.

24. As found by the Subcommittee, the Defendants have willfully sold—and continue to sell—contaminated Baby Foods notwithstanding their full awareness of these unacceptably high levels of Toxic Heavy Metals in their products.

III. Dangers of Toxic Heavy Metals to Babies and Children

25. According to the World Health Organization (“WHO”), Toxic Heavy Metals, specifically lead and arsenic pose a “major public health concern” for children.¹⁸ The Occupational Safety and Health Administration (“OSHA”) has warned that these metals “may build up in

¹⁸ World Health Organization, *Children’s Health and the Environment WHO training Package for the Health Sector* (October 2011), available at: https://www.who.int/ceh/capacity/heavy_metals.pdf.

biological systems and become a significant health hazard.”¹⁹ Indeed, the Department of Health and Human Services’ Agency for Toxic Substances and Disease Registry (“ATSDR”) ranks arsenic as number *one* among substances present in the environment that pose the most significant potential threat to human health, followed by lead (second), and mercury (third).

26. The threat presented by Toxic Heavy Metals to children’s health is widely shared by the global scientific community. For example, the FDA has set an Interim Reference Level (“IRL”) of 2.2 micrograms/day for lead exposure through baby food products.²⁰ That is the amount of lead exposure above which the agency considers associated with adverse neurological effects in babies. None of the Defendant Baby Food Manufacturers have ever conducted any tests or analyses to determine whether exposure to lead from their baby food products would result in children having blood lead amounts of 2.2 micrograms/day. The FDA, in its guidance documents for inorganic arsenic and lead in baby food products has repeatedly acknowledged the dangers of heavy metals to the neurodevelopment of infants.

Even low lead exposure can harm children’s health and development, specifically the brain and nervous system. Neurological effects of lead exposure during early childhood include learning disabilities, behavior difficulties, and lowered IQ. Lead exposures also may be associated with immunological, cardiovascular, renal, and reproductive and/or developmental effects...Because lead can accumulate in the body, even low-level chronic exposure can be hazardous over time...Even though no safe level of lead exposure has yet been identified for children’s health, the IRL serves as a useful benchmark in evaluating the potential for adverse effects of dietary lead. In particular, FDA is focused on the potential for neurodevelopmental effects from lead exposure, as review of the scientific literature indicates that *such adverse effects of lead consistently occur at a blood lead level associated with FDA’s IRL for children*. (emphasis added).²¹

27. As one recent study observed, “[t]he implications of heavy metals with regards to children’s health have been noted to be more severe compared to adults. The elements’ harmful consequences on children health include mental retardation, neurocognitive disorders, behavioral disorders, respiratory problems, cancer and cardiovascular diseases. Much attention should be given

¹⁹ OSHA, *Toxic Metals*, available at: <https://www.osha.gov/toxic-metals>.

²⁰ FDA (January 2023) *Action Levels for Lead in Food Intended for Babies and Young Children: Draft Guidance For Industry*, available at: <https://www.fda.gov/media/164684/download>.

²¹ *Id.*

to heavy metals because of their high toxicity potential, widespread use, and prevalence.”²² Children and, even more so, babies have higher exposure to metals compared to adults because they consume more food in relation to their body weight and absorb metals more readily than adults by 40 to 90%.²³ And, the mechanisms needed to metabolize and eliminate heavy metals are comparatively undeveloped in childhood, with babies having weaker detoxifying mechanisms and poorer immune systems than adults.²⁴ For example, liver pathways that in adulthood metabolize absorbed arsenic do not mature until mid-childhood; un-excreted arsenic thus continues to circulate and is deposited in other organs.²⁵ According to Linda McCauley, Dean of the Nell Hodgson Woodruff School of Nursing at Emory University, who studies environmental health effects, “[n]o level of exposure to these [heavy] metals has been shown to be safe in vulnerable infants.”²⁶ Thus, “the major windows of developmental vulnerability occur during infancy and early childhood due to continuing brain development after birth.”²⁷ In short, even small amounts of exposure to Toxic Heavy Metals can have devastating health outcomes for babies and children.

28. Notably, none of the Defendants ever conducted any kind of risk assessments or analyses to determine whether exposure to their baby food products exposed children to lead amounts known to harm neurodevelopment. On information and belief, exposure to Defendants’ Baby Food products exposed Plaintiff to heavy metal concentrations known to result in brain injury.

A. Exposure to Toxic Heavy Metals Has Been Consistently Associated with Brain Injury, i.e., Autism and ADHD in Pediatric Populations

²² Osman, et al., *Exposure routes and health effects of heavy metals on children*, 32 BIOMETALS 563–573 (2019), available at: <https://link.springer.com/article/10.1007%2Fs10534-019-00193-5#citeas>.

²³ Stein, et al., *In harm’s way: toxic threats to child development*, 23 J DEV BEHAV PEDIATR.1 S13–S22 (2002).

²⁴ Gorini, et al., *The Role of Heavy Metal Pollution in Neurobehavioral Disorders: a Focus on Autism* 1 REV. J. AUTISM DEV. DISORD. 1, 354–372 (2014), available at: <https://link.springer.com/article/10.1007/s40489-014-0028-3>.

²⁵ Del Rio, et al., *A comparison of arsenic exposure in young children and home water arsenic in two rural West Texas communities* 17 BMC PUBLIC HEALTH 850 1-13 (2017), available at: <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-017-4808-4>.

²⁶ Roni Caryn Rabin, *Some Baby Food May Contain Toxic Metals*, U.S. Reports (NY TIMES, Feb 4, 2021), available at: <https://www.nytimes.com/2021/02/04/health/baby-food-metals-arsenic.html>

²⁷ Gorini, et al. *supra*.

29. It is well-known that exposure to heavy metals in early life can cause brain injury at low levels of exposure. And one of the ways in which such brain injury can present in a child is in the form of the neurodevelopmental disorders ASD and ADHD. As the U.S. Centers for Disease Control observed in its 2020 Toxicological Profile for Lead, at just ≤ 10 $\mu\text{g/dL}$: “The following neurobehavioral effects in children have been associated with [lead]: “Altered mood and behaviors that may contribute to learning deficits, including *attention deficits, hyperactivity, autistic behaviors, conduct disorders, and delinquency.*”²⁸ (emphasis added). Likewise, the NIH states: “prenatal and early childhood exposure to heavy metals...may be linked to autism spectrum disorder.”²⁹

30. Multiple studies, reviews, and meta-analyses conducted throughout various parts of the world over the last decade have consistently observed that early life exposure to heavy metals can cause brain injury and, specifically, brain injury which manifests as ASD.

31. For example, four meta-analyses published in 2014, 2017, 2019 and 2020, respectively, all observed a consistent association between exposure to arsenic and mercury and ASD in children; with the authors in all three studies recommending – based on the data – that exposure to such metals in children be reduced as much as possible, and one of the study authors specifically concluding that “Results of the current meta-analysis revealed that mercury is an important causal factor in the etiology of ASD.”³⁰

32. In a recent 2017 NIH-funded prospective observational study, the authors examined the risk of ASD outcome in twins based on their respective body burden of lead. The study

²⁸ ATSDR (2020) *Toxicological Profile for Lead*, available at: <https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf>.

²⁹ NIH, ASD & the Environment.

³⁰ Jafari, et al., *The association between mercury levels and autism spectrum disorders: A systematic review and meta-analysis* 44 J. TRACE. ELEMEN. IN MED. & BIOL. 289-297 (2017); Wang, et al., *Exposure to Inorganic Arsenic and Lead and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 21 CHEM RES. TOXICOL. 32, 1904-1919 (2019), available at: <https://pubmed.ncbi.nlm.nih.gov/31549506/>; Sulaiman, et al., *Exposure to Aluminum, Cadmium, and Mercury and Autism Spectrum Disorder in Children: A Systematic Review and Meta-Analysis*, 33 Chem. Res. Toxicol. 11, 2699-2718 (2020), available at: <https://pubmed.ncbi.nlm.nih.gov/32990432/>; Yoshimasu, et al., *A meta-analysis of the evidence on the impact of prenatal and early infancy exposures to mercury on autism and attention deficit/hyperactivity disorder in the childhood*, 44 NEURO TOXICOL. 121-131 (2014), available at: <https://pubmed.ncbi.nlm.nih.gov/24952233/>.

concluded in no uncertain terms that “prenatal and early childhood disruption (excess or deficiency) of multiple metals during critical developmental windows is associated with ASD, and suggests a role for elemental dysregulation in the etiology of ASD.”³¹

33. Similarly, a large, prospective study from 2016 in Korean school children observed that low levels of lead exposure in early life are associated with autism, the authors specifically concluding: “even low blood lead concentrations...are associated with more autistic behaviors..., underscoring the need for continued efforts to reduce lead exposure.”³²

34. Furthermore, repeated associations between early life metal exposure and ASD have also been observed during the pre-natal timeframe, lending further strength to the findings of post-natal studies. For example, in a 2021 study by Skogheim and colleagues, the authors prospectively assessed the relationship between pre-natal metal exposure in various biomarkers and autism risk. The study concluded that “[r]esults from the present study show several associations between levels of metals and elements during gestation and ASD and ADHD in children. The most notable ones involved arsenic...mercury...and lead. Our results suggest that even population levels of these compounds may have negative impacts on neurodevelopment.”³³ Similarly, in a study by the research group assessing the New Hampshire Birth Cohort, the authors evaluated the neurotoxic effects of heavy metals during various stages of pregnancy and concluded: “Our results support the hypothesis that exposure to...As in mid to late pregnancy may be neurodevelopmentally harmful.”³⁴

35. Moreover, such results have been replicated in studies throughout the world, including China, Korea, the U.S., Europe, and Egypt, implicating arsenic, mercury, and lead in pediatric diagnoses of autism and autistic behaviors, with a 2018 Chinese study concluding: “[t]he results of

³¹ Arora, et al., *Fetal and postnatal metal dysregulation in autism* NATURE COMM. 1-10 (2017), available at: <https://www.nature.com/articles/ncomms15493>.

³² Kim, et al., *Low-Level lead Exposure and Autistic Behaviors in School-Age Children*, 53 NEUROTOXICOLOGY 193-200 (2016).

³³ Skogheim, et al. *Metal and essential element concentrations during pregnancy and associations with autism spectrum disorder and attention-deficit/ hyperactivity disorder in children* 152 1-14 (2021).

³⁴ Doherty, et al., *Periconceptional and prenatal exposure to metal mixtures in relation to behavioral development at 3 years of age* 4 ENVIRON. EPIDEMIOL. (2020).

1 this study are consistent with numerous previous studies, supporting an important role for heavy
 2 metal exposure, particularly mercury, in the etiology of ASD.³⁵ Indeed, a 2015 Egyptian study noted
 3 “[e]nvironmental exposure to these toxic heavy metals, *at key times in development*, may play a
 4 causal role in autism.” (emphasis added).³⁶

5 36. Exposure to Toxic Heavy Metals, specifically lead, has also been repeatedly
 6 associated with the development of ADHD in children, as demonstrated by numerous studies.

7 37. No fewer than four large meta-analyses, conducted in four different continents (North
 8 America, South America, Europe and Asia), and some employing a cross-sectional design, have
 9 observed a consistent associated association between various metals and ADHD in children.³⁷
 10 Indeed, the authors of the meta-analysis from Spain noted that “the evidence from the studies allowed
 11 us to establish that there is an association between lead and ADHD and that even *low levels of lead*
 12 *raise the risk*.” (emphasis added).³⁸

13 38. The findings from the meta-analyses have been replicated in several Chinese studies
 14

15 ³⁵ Li, et al., *Blood Mercury, Arsenic, Cadmium, and Lead in Children with Autism Spectrum*
 16 *Disorder*, 181 BIOL TRACE ELEM RES 31-37 (2018), available at:
 17 <https://pubmed.ncbi.nlm.nih.gov/28480499/>; Ryu, et al., *Associations of prenatal and early childhood*
 18 *mercury exposure with autistic behaviors at 5 years of age: The Mothers and Children's*
 19 *Environmental Health (MOCEH) study*, 15 SCI. TOTAL ENVIRON. 251-257 (2017), available at:
 20 <https://www.sciencedirect.com/science/article/abs/pii/S0048969717316479>; Dickerson, et al., *Autism*
 21 *spectrum disorder prevalence and associations with air concentrations of lead, mercury, and arsenic*,
 22 188 ENVIRON MONIT. ASSESS. 407 (2016); Mohamed, et al., *Assessment of Hair Aluminum, Lead, and*
 23 *Mercury in a Sample of Autistic Egyptian Children: Environmental Risk Factors of Heavy Metals in*
 24 *Autism BEHAV. NEUROL.* (2015), available at: <https://pubmed.ncbi.nlm.nih.gov/26508811/>; Adams, et
 25 al., *Toxicological Status of Children with Autism vs. Neurotypical Children and the Association with*
 26 *Autism Severity*, 151 BIOL. TRACE ELEM. RES 171-180 (2013), available at:
 27 <https://pubmed.ncbi.nlm.nih.gov/23192845/>.

28 ³⁶ Mohamed, et al.

³⁷ Muñoz, et al., *Attention deficit hyperactivity disorder and its association with heavy metals in*
 children from northern Chile, 226 INT. J. HYG. ENVIRON. HEALTH (2020), available at:
<https://europepmc.org/article/med/32106053>; Yoshimasu, et al., *supra*; Donzelli, et al., *The*
Association between Lead and Attention-Deficit/Hyperactivity Disorder: A Systematic Review, 16
 INT. J. ENVIRON. RES. PUBLIC HEALTH 382, 1-14 (2019), available at:
<https://pubmed.ncbi.nlm.nih.gov/30700018/>; Goodland, et al., *Lead and Attention-*
Deficit/Hyperactivity Disorder (ADHD) symptoms: A meta-analysis, 33 CLIN. PSYCHOL. REV. 3, 417-
 242 (2013), available at: <https://pubmed.ncbi.nlm.nih.gov/23419800/>.

³⁸ Donzelli et al, *supra*.

from 2006, 2014 and 2018, respectively.³⁹ Notably, the authors of the 2014 Chinese study observed that “[e]xposure to lead even at low levels correlates with attention-deficit/hyperactivity disorder (ADHD). However, lead-contaminated environments are often *contaminated with other heavy metals that could exacerbate lead-induced ADHD*.” (emphasis added).⁴⁰ This is particularly relevant—and disturbing—as children who consumed Defendants’ Baby Food were repeatedly exposed to a cocktail of Toxic Heavy Metals that, synergistically, further increased their risk of developing ADHD.

39. Moreover, studies have observed a dose-response relationship between exposure to Toxic Heavy Metals and ADHD, as demonstrated by the 2016 Spanish study Donzelli, *et al.* discussed *supra*. Another 2016 cross-sectional study from Spain was conducted on 261 children aged 6-9 to examine the association between exposure to arsenic and ADHD.⁴¹ After adjusting for potential confounders, the authors observed a dose-response relationship between urine arsenic levels and inattention and impulsivity scores, concluding that “[urine arsenic] levels were associated with impaired attention/cognitive function, *even at levels considered safe*. These results provide additional evidence that postnatal arsenic exposure impairs neurological function in children.”⁴² (emphasis added).

40. The fact that such results, and many more, have been observed in multiple studies, conducted by different researchers, at different times, in different parts of the world, in children of multiple ages, utilizing different study methods (prospective, case-control and cross-sectional

³⁹ Lee, et al., *Heavy Metals’ Effect on Susceptibility to Attention-Deficit/Hyperactivity Disorder: Implication of Lead, Cadmium, and Antimony*, 15 INT. J. ENVIRON. RES. PUBLIC HEALTH. 6, 1-2 (2018), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6025252/>; Liu, et al., *S100β in heavy metal-related child attention-deficit hyperactivity disorder in an informal e-waste recycling area*, 45 NEURO TOXICOL. 185-191 (2014), available at: <https://www.sciencedirect.com/science/article/abs/pii/S0161813X14001831>; Wong, V.C.N., *Attention-Deficit Hyperactivity Disorder and Blood Mercury Level: a Case-Control Study in Chinese Children*, 37 NEUROPEDIATRICS 4, 234-40 (2006), available at: https://www.researchgate.net/publication/6623327_Attention-Deficit_Hyperactivity_Disorder_and_Blood_Mercury_Level_a_Case-Control_Study_in_Chinese_Children.

⁴⁰ Liu, et al. *supra*

⁴¹ Rodriguez-Barranco, et al., *Postnatal arsenic exposure and attention impairment in school children*, 74 CORTEX 370-382 (2016).

⁴² *Id.*

epidemiological analyses) and measuring a variety of end-points (including hair, blood, and urine), strongly supports a causal relationship between exposure to Toxic Heavy Metals and the development of ASD and ADHD in children.

IV. Defendants Knowingly Sold Baby Foods Containing Dangerous Levels of Toxic Heavy Metals and Knew or Should Have Known of the Risks of Such Exposures in Children

41. During the time that Defendants manufactured and sold Baby Foods in the United States, the weight of evidence showed that Defendants' Baby Foods exposed babies and children to unsafe levels of Toxic Heavy Metals. Defendants failed to disclose this risk to consumers through any means.

42. As discussed above, both independent testing, the Defendants' internal evaluations of their Baby Foods, and the Defendants' representations and disclosures to the Subcommittee and FDA reveal the presence of substantial amounts of Toxic Heavy Metals in Defendants' products. As such, Defendants knew or should have known that their Baby Foods contain dangerous of Toxic Heavy Metals.

43. Indeed, independent testing performed in early 2019 demonstrated elevated amounts of such Toxic Heavy Metals in Baby Food products on the U.S. market,⁴³ and the HBBF Report further confirmed such contamination of Defendants' Baby Foods.⁴⁴ And, as the Subcommittee found, the Defendants continued to sell their Baby Foods even after testing of both ingredients and finished products revealed the presence of substantial amounts of Toxic Heavy Metals.⁴⁵

44. Moreover, the scientific literature on the dangers of Toxic Heavy Metals—particularly as it relates to adverse effects on the neurodevelopment of children—have been well known for decades. Defendants, as manufacturers and retailers of Baby Foods, are held to the standard of experts responsible for keeping abreast of the latest scientific developments related to the dangers of contaminants in their products. Furthermore, as alleged in more detail below, the Retailer Defendant is strictly liable for selling the Baby Foods which caused Plaintiff's harm. Defendants failed to take

⁴³ See Gardener, et al., *supra*.

⁴⁴ See HBBF Report, *supra*.

⁴⁵ See, e.g., Subcommittee Report at 13-14.

1 action in protecting vulnerable children from exposure to the Toxic Heavy Metals in their foods and,
 2 thus, subjected them to the risk of brain injury which can manifest as neurodevelopmental disorders
 3 such as ASD, ADHD, and related *sequelae*.

4 45. To be clear, the Defendants are able to manufacture Baby Foods that do not pose such
 5 a dangerous risk to the health of infants and children by using alternative ingredients, not adding
 6 certain pre-mix minerals and vitamins high in Toxic Heavy Metals, or sampling their ingredients
 7 from other sources, as specifically acknowledged by Hain in its August 2019 presentation to the
 8 FDA: “Explore alternatives for Brown Rice ingredient to reduce risk.”⁴⁶ At the very least,
 9 Defendants were under a duty to warn unsuspecting parents of the presence of Toxic Heavy Metals in
 10 their Baby Foods. However, Defendants took no action, continued to sell their products with full
 11 knowledge of the risks posed by their Baby Foods, and misled consumers regarding the safety of their
 12 products, all to the harm of children.

13 **V. Exemplary / Punitive Damages Allegations**

14 46. Defendants’ conduct as alleged herein was done with reckless disregard for human
 15 life, oppression, and malice. Defendants’ conduct is particularly reprehensible given that their toxic
 16 foods were directed at vulnerable babies—a population group far more susceptible than adults to the
 17 neurotoxic dangers of heavy metals.

18 47. Defendants were fully aware of the safety risks of Baby Foods, particularly the
 19 dangerous potential of their Baby Foods given the high content of Toxic Heavy Metals that have all
 20 been associated with brain injury in children. Nonetheless, Defendants deliberately crafted their
 21 label, marketing, and promotion to mislead consumers. Indeed, Defendants repeatedly market their
 22 Baby Foods as safe for consumption and go so far as claiming that they adhere to “the strictest
 23 standards in the world”; and provide “baby’s food full of nutrition while meeting standards strict
 24 enough for tiny tummies” as well as other statements and representations that hold out their Baby
 25 Foods as safe for consumption by infants. In actual fact, as discussed above, Defendants routinely
 26 sold Baby Foods containing astronomical amounts of Toxic Heavy Metals, regularly flouted their

27 _____
 28 ⁴⁶ 2019 Hain & FDA Meeting at *10.

own internal limits of Toxic Heavy Metals in Baby Foods and failed to disclose to consumers that their products contained such dangerous contaminants.

48. This was not done by accident or through some justifiable negligence. Rather, Defendants knew they could profit by convincing consumers that their Baby Foods were harmless to humans, and that full disclosure of the true risks of the Toxic Heavy Metals present in the Baby Foods would limit the amount of money Defendants would make selling the products. Defendants' object was accomplished not only through a misleading label, but through a comprehensive scheme of selective misleading research and testing, failure to test, false advertising, and deceptive omissions as more fully alleged throughout this pleading. Parents were denied the right to make an informed decision about whether to purchase and Defendants' Baby Food for their children, knowing the full risks attendant to that use. Such conduct was done with conscious disregard of Plaintiff's rights.

49. Accordingly, Plaintiff requests punitive damages against the Defendants for the harms caused to Plaintiff pursuant to Nev. Res. Stat. §42.005.

PLAINTIFF-SPECIFIC ALLEGATIONS

50. Plaintiff, A.V., was diagnosed with ASD at approximately three years of age.

51. A.V. started consuming Baby Food products, including but not limited to rice cereal and puffs, manufactured and/or sold by the Defendants in approximately 2021 and consumed Defendants' Baby Food products at various times through early childhood.

52. Upon information and belief, the Baby Food products manufactured/marketed by Defendants and consumed by A.V. were all contaminated with substantial quantities of Toxic Heavy Metals, namely lead, arsenic, and mercury – exceeding that of any regulatory limits.

53. Upon information and belief, as a direct and proximate result of consuming Defendants' Baby Foods, A.V. was exposed to substantial quantities of Toxic Heavy Metals, namely lead, arsenic, and mercury.

54. As a direct and proximate result of consuming Defendants' Baby Foods and the exposure to the Toxic Heavy Metals therein – A.V. suffered brain injury which manifested as ASD and related *sequelae*.

55. Based on prevailing scientific evidence, exposure to the Toxic Heavy Metals at the

1 levels contained in Defendants' Baby Foods can cause brain injury which can manifest as the
2 neurodevelopmental disorders ASD and related *sequae* in humans.

3 56. Ashley Garcia is the mother of Plaintiff, A.V., and brings this suit on his behalf as
4 well as individually to the extent she is entitled to compensation for medical expenses she incurred
5 related to the care and treatment of A.V. for autism.

6 57. Had any Defendant warned Plaintiff's carers that Defendants' Baby Foods could lead
7 to exposure to Toxic Heavy Metals or, in turn, brain injury, A.V. would not have consumed the Baby
8 Foods.

9 58. A.V. alleges that as a direct and proximate result of A.V.'s consumption of Baby
10 Foods supplied and distributed by Defendants, A.V. suffered significant harm, conscious pain and
11 suffering, physical injury and bodily impairment including, but not limited to brain injury which
12 manifested as ASD and related *sequae*.

13 **CAUSES OF ACTION**

14 **COUNT I: STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

15 59. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
16 if fully stated herein.

17 60. At all relevant times, Defendants engaged in the business of researching, testing,
18 developing, designing, manufacturing, labeling, marketing, selling, inspecting, distributing, and
19 promoting Baby Foods, which are defective and unreasonably dangerous to consumers, including
20 Plaintiff, because they do not contain adequate warnings or instructions concerning the dangerous
21 characteristics of Baby Foods and Toxic Heavy Metals. These actions were under the ultimate
22 control and supervision of Defendants. At all relevant times, Defendants registered, researched,
23 manufactured, distributed, marketed, and sold Baby Foods and aimed at a consumer market.

24 61. Defendants researched, tested, developed, designed, manufactured, labeled, marketed,
25 sold, inspected, distributed, and promoted, and otherwise released into the stream of commerce their
26 Baby Foods, and in the course of same, directly advertised or marketed the products to consumers
27 and end users, including Plaintiff, and therefore had a duty to warn of the risks associated with the
28 consumption of Baby Foods.

1 62. At all relevant times, Defendants had a duty to properly test, develop, design,
2 manufacture, inspect, package, label, market, promote, sell, and distribute, maintain, supply, provide
3 proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and
4 consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to
5 warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or
6 distributor of food, are held to the knowledge of an expert in the field.

7 63. At the time of manufacture, Defendants could have provided the warnings or
8 instructions regarding the full and complete risks of Baby Foods because they knew or should have
9 known of the unreasonable risks of harm associated with the use of and/or exposure to such products.

10 64. At all relevant times, Defendants failed and deliberately refused to investigate, study,
11 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
12 those who would foreseeably use or be harmed by Defendants' Baby Foods.

13 65. Even though Defendants knew or should have known that Baby Foods posed a grave
14 risk of harm, they failed to exercise reasonable care to warn of the dangerous risks associated with
15 use and exposure to the products. The dangerous propensities of their products and the neurotoxic
16 characteristic of Toxic Heavy Metals contained in Defendants' Baby Foods, as described above, were
17 known to Defendants, or scientifically knowable to Defendants through appropriate research and
18 testing by known methods, at the time they distributed, supplied or sold the product, and were not
19 known to end users and consumers, such as Plaintiff. The product warnings for Baby Foods in effect
20 during the time period Plaintiff consumed Baby Foods were vague, incomplete or otherwise
21 inadequate, both substantively and graphically, to alert consumers to the severe health risks
22 associated with Baby Foods consumption.

23 66. Defendants knew or should have known that their products created significant risks of
24 serious bodily harm to consumers, as alleged herein, and Defendants failed to adequately warn or
25 instruct consumers, i.e., the reasonably foreseeable users, of the risks of exposure to their products.
26 Defendants failed to warn and have wrongfully concealed information concerning the dangerous
27 level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby Foods to
28 expose children to Toxic Heavy Metals, and further, have made false and/or misleading statements

1 concerning the safety of Baby Foods.

2 67. At all relevant times, Defendants' Baby Foods reached the intended consumers,
3 handlers, and users or other persons coming into contact with these products, including Plaintiff,
4 without substantial change in their condition as designed, manufactured, sold, distributed, labeled,
5 and marketed by Defendants.

6 68. Plaintiff was exposed to Defendants' Baby Foods without knowledge of their
7 dangerous characteristics.

8 69. At all relevant times, Plaintiff was exposed to Defendants' Baby Foods while using
9 them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous
10 characteristics.

11 70. Plaintiff could not have reasonably discovered the defects and risks associated with
12 Baby Foods prior to or at the time of Plaintiff consuming Baby Foods. Plaintiff relied upon the skill,
13 superior knowledge, and judgment of Defendants to know about and disclose serious health risks
14 associated with using Defendants' products.

15 71. Defendants knew or should have known that the information disseminated with their
16 Baby Foods were inadequate, failed to communicate adequate information on the dangers of
17 consumption, and failed to communicate warnings and instructions that were appropriate and
18 adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

19 72. The information that Defendants did provide or communicate failed to contain
20 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
21 avoid consuming the products. Instead, Defendants disseminated information that was inaccurate,
22 false, and misleading, and which failed to communicate accurately or adequately the comparative
23 severity, duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods;
24 continued to aggressively promote the safety of their products, even after they knew or should have
25 known of the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise
26 suppressed, through aggressive marketing and promotion, any information or research about the risks
27 and dangers of consuming Baby Foods.

28 73. This alleged failure to warn is not limited to the information contained on Baby Foods

1 labeling. The Defendants were able, in accord with federal law, to comply with relevant state law by
2 disclosing the known risks associated with Baby Foods through other non-labeling mediums, *i.e.*,
3 promotion, advertisements, public service announcements, and/or public information sources. But
4 the Defendants did not disclose these known risks through any medium. The ability to provide such
5 warnings is not prohibited by any federal law.

6 74. Furthermore, Defendants possess a First Amendment Right to make truthful
7 statements about the products they sell, and no law could lawfully restrict that constitutional right.

8 75. Had Defendants provided adequate warnings and instructions and properly disclosed
9 and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of
10 developing injuries and could have obtained or used alternative products. However, as a result of
11 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted
12 his injuries.

13 76. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
14 babies and children, including Plaintiff, with knowledge of the safety problems associated with Baby
15 Foods, and suppressed this knowledge from the general public. Defendants made conscious decisions
16 not to redesign, warn or inform the unsuspecting public. Defendants' reckless conduct warrants an
17 award of punitive damages.

18 77. The Defendants' lack of adequate warnings and instructions accompanying their Baby
19 Foods were a substantial factor in causing Plaintiff's injuries.

20 78. As a direct and proximate result of the Defendants' failure to provide an adequate
21 warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
22 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
23 not limited to past and future medical expenses, lost income, and other damages.

24 79. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in
25 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
26 other and further relief as this Court deems just and proper.

27 **COUNT II: STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

28 80. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as

1 if fully stated herein.

2 81. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
3 sold, handled, and distributed the Baby Foods consumed by Plaintiff. These actions were under the
4 ultimate control and supervision of Defendants.

5 82. At all relevant times, Defendants' Baby Food products were manufactured, designed,
6 and labeled in an unsafe, defective, and inherently dangerous manner that was dangerous for use by
7 or exposure to infants and babies, including Plaintiff.

8 83. Defendants' Baby Food products as researched, tested, developed, designed, licensed,
9 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
10 design and formulation in that, when they were placed into the stream of commerce, they were
11 unreasonably dangerous and dangerous to an extent beyond that which an ordinary consumer would
12 contemplate.

13 84. Defendants' Baby Food products, as researched, tested, developed, designed, licensed,
14 manufactured, packaged, labeled, distributed, sold, and marketed by Defendants were defective in
15 design and formulation in that, when they left the hands of Defendants', the foreseeable risks
16 exceeded the alleged benefits associated with their design and formulation.

17 85. At all relevant times, the Baby Food products consumed by Plaintiff was expected to
18 and did reach Plaintiff without a substantial change in its condition as manufactured, handled,
19 distributed, and sold by Defendants.

20 86. At all relevant times, Defendants knew or had reason to know that their Baby Food
21 products were defective and were inherently dangerous and unsafe when used in the manner
22 instructed and provided by Defendants.

23 87. Therefore, at all relevant times, Defendants' Baby Food products, as researched,
24 tested, developed, designed, registered, licensed, manufactured, packaged, labeled, distributed, sold
25 and marketed by Defendants were defective in design and formulation, in one or more of the
26 following ways:

27 When placed in the stream of commerce, Defendants' Baby Food products were unreasonably
28 dangerous in that they were hazardous and posed a grave risk of causing brain injury that manifests as

1 the neurodevelopmental disorders ASD and related *sequelae* when used in a reasonably anticipated
2 manner due to the substantial quantities of Toxic Heavy Metals in the Baby Foods; When placed in
3 the stream of commerce, Defendants' Baby Food products contained unreasonably dangerous design
4 defects and were not reasonably safe when used in a reasonably anticipated or intended manner;
5 Defendants did not sufficiently test, investigate, or study their Baby Food products; Exposure to the
6 Toxic Heavy Metals in Defendants' Baby Food products present a risk of harmful effects that
7 outweigh any potential utility stemming from their use; Defendants knew or should have known at
8 the time of marketing Baby Food products that exposure to their Baby Food products could result in
9 brain injury that manifests as ASD and related *sequelae* in children; Defendants did not conduct
10 adequate post-marketing surveillance of their Baby Food products; and Defendants could have
11 employed safer alternative designs and formulations.

12 88. Plaintiff consumed Defendants' Baby Food products in an intended or reasonably
13 foreseeable manner without knowledge of their dangerous characteristics.

14 89. Defendants' Baby Food products were and are more dangerous than alternative
15 products, and Defendants could have designed their Baby Food products to avoid harm to children.
16 Indeed, at the time Defendants designed the Baby Food products, the state of the industry's scientific
17 knowledge was such that a less risky design or formulation was attainable.

18 90. At the time the Baby Food products left Defendants' control, there was a practical,
19 technically feasible and safer alternative design that would have prevented the harm without
20 substantially impairing the reasonably anticipated or intended function of Defendants' Baby Foods,
21 as for example, demonstrated by Hain's presentation to the FDA wherein Hain acknowledges the risk
22 posed by specific ingredients in its Baby Foods.

23 91. Defendants have intentionally and recklessly defectively designed the Baby Foods
24 with wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing
25 their economic interests above the health and safety of the Plaintiff.

26 92. The design defects in Defendants' Baby Foods were substantial factors in causing
27 Plaintiff's injuries.

28 93. As a direct and proximate result of the Defendants' defective design of the Baby

1 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
2 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to
3 medical expenses, lost income, and other damages.

4 **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's
5 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
6 further relief as this Court deems just and proper.

7 **COUNT III: STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

8 94. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
9 if fully stated herein.

10 95. At all times herein mentioned, Defendants designed, manufactured, tested, marketed,
11 sold, handled, and distributed the Baby Foods consumed by Plaintiff.

12 96. At all relevant times, the Baby Foods consumed by Plaintiff was expected to and did
13 reach Plaintiff without a substantial change in its condition as manufactured, handled, distributed, and
14 sold by Defendants.

15 97. At all relevant times, the Baby Foods consumed by Plaintiff was used in a manner that
16 was foreseeable and intended by Defendants.

17 98. The Baby Foods consumed by Plaintiff was not reasonably safe for their intended use
18 and were defective with respect to their manufacture, as described herein, in that Defendants deviated
19 materially from their design and manufacturing specifications and/or such design and manufacture
20 posed an unreasonable risk of harm to Plaintiff.

21 99. The Defendants' Baby Foods are inherently dangerous and defective, unfit and unsafe
22 for its intended and reasonably foreseeable uses, and do not meet or perform to the expectations of
23 parents or children.

24 100. The Baby Foods create risks to the health and safety of babies that are far more
25 significant and devastating than the risks posed by other baby food products, and which far outweigh
26 the utility of the Baby Foods products because of Defendants' manufacturing defects, which included
27 but were not limited to: Failure to adequately inspect/test the Baby Foods during the manufacturing
28 process; Failure to implement procedures that would reduce or eliminate the levels of Toxic Heavy

1 Metals in Baby Foods; Failure to avoid using ingredients free from, or which contain far less, Toxic
2 Heavy Metals to manufacture Baby Foods.

3 101. Defendants have intentionally and recklessly manufactured the Baby Foods with
4 wanton and willful disregard for the rights and health of the Plaintiff, and with malice, placing their
5 economic interests above the health and safety of the Plaintiff.

6 102. The manufacturing defects in Defendants' Baby Foods were substantial factors in
7 causing Plaintiff's injuries.

8 103. As a direct and proximate result of the Defendants' defective manufacture of the Baby
9 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
10 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to
11 medical expenses, lost income, and other damages.

12 **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in Plaintiff's
13 favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and
14 further relief as this Court deems just and proper.

15 **COUNT IV: NEGLIGENCE – FAILURE TO WARN**

16 104. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
17 if fully stated herein.

18 105. At all relevant times, Defendants engaged in the business of testing, developing,
19 designing, manufacturing, marketing, selling, distributing, and promoting Baby Foods. Defendants
20 knew or by the exercise of reasonable care should have known that their Baby Foods are not
21 accompanied with adequate warnings concerning the dangerous characteristics of Baby Foods and
22 Toxic Heavy Metals. These actions were under the ultimate control and supervision of Defendants.

23 106. Defendants researched, developed, designed, tested, manufactured, inspected, labeled,
24 distributed, marketed, promoted, sold, and otherwise released into the stream of commerce their Baby
25 Foods, and in the course of same, directly advertised or marketed the products to consumers and end
26 users, including Plaintiff, and therefore had a duty to warn of the risks associated with the use of
27 Baby Foods.

28 107. At all relevant times, Defendants had a duty to properly test, develop, design,

1 manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide
2 proper warnings, and take such steps as necessary to ensure their Baby Foods did not cause users and
3 consumers to suffer from unreasonable and dangerous risks. Defendants had a continuing duty to
4 warn Plaintiff of dangers associated with Baby Foods. Defendants, as a manufacturer, seller, or
5 distributor of food products, are held to the knowledge of an expert in the field.

6 108. At the time of manufacture, Defendants could have provided warnings regarding the
7 full and complete risks of Baby Foods and Toxic Heavy Metals because they knew or should have
8 known use of Baby Foods was dangerous, harmful and injurious when used by Plaintiff in a
9 reasonably foreseeable manner.

10 109. At all relevant times, Defendants failed and deliberately refused to investigate, study,
11 test, or promote the safety or to minimize the dangers to users and consumers of their product and to
12 those who would foreseeably use or be harmed by Defendants' Baby Foods.

13 110. Defendants knew or should have known that Baby Foods posed a grave risk of harm,
14 but failed to exercise reasonable care to warn of the dangerous risks associated with use and exposure
15 to the products. The dangerous propensities of their products and the characteristics of Toxic Heavy
16 Metals contained in substantial amounts in their Baby Foods, as described above, were known to
17 Defendants, or scientifically knowable to Defendants through appropriate research and testing by
18 known methods, at the time they distributed, supplied or sold the product, and were not known to end
19 users and consumers, such as the Plaintiff.

20 111. Defendants further breached their duty by failing to use reasonable care to adequately
21 warn or instruct consumers (*i.e.*, the reasonably foreseeable users) of the risks of exposure to their
22 products. Defendants failed to warn and have wrongfully concealed information concerning the
23 dangerous level of Toxic Heavy Metals in their Baby Foods and the potential for consumed Baby
24 Foods to expose babies and toddlers to Toxic Heavy Metals, and further, have made false and/or
25 misleading statements concerning the safety of Baby Foods.

26 112. At all relevant times, Plaintiff was exposed to excessive levels of Toxic Heavy Metals
27 through consumption of Toxic Heavy Metals while using them for their intended or reasonably
28 foreseeable purposes, without knowledge of their dangerous characteristics.

1 113. Defendants knew or should have known that the minimal warnings disseminated with
2 their Baby Foods were inadequate, failed to communicate adequate information on the dangers and
3 safe use/exposure, and failed to communicate warnings and instructions that were appropriate and
4 adequate to render the products safe for their ordinary, intended and reasonably foreseeable uses.

5 114. The information that Defendants did provide or communicate failed to contain
6 relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff to
7 avoid using the product. Instead, Defendants disseminated information that was inaccurate, false, and
8 misleading, and which failed to communicate accurately or adequately the comparative severity,
9 duration, and extent of the risk of injuries with use of and/or exposure to Baby Foods; continued to
10 aggressively promote the efficacy of their products, even after they knew or should have known of
11 the unreasonable risks from use or exposure; and concealed, downplayed, or otherwise suppressed,
12 through aggressive marketing and promotion, any information or research about the risks and dangers
13 of consuming Baby Foods.

14 115. A reasonable company under the same or similar circumstance would have warned
15 and instructed of the dangers of Baby Foods and Toxic Heavy Metals contained therein.

16 116. This alleged failure to warn is not limited to the information contained on the labeling
17 of Defendants' Baby Foods. Defendants were able, in accord with federal law, to comply with
18 relevant state law by disclosing the known risks associated with Baby Foods and Toxic Heavy Metals
19 through other non-labeling mediums, *i.e.*, promotion, advertisements, public service announcements,
20 and/or public information sources. But the Defendants did not disclose these known risks through
21 any medium.

22 117. Furthermore, Defendants possess a First Amendment Right to make truthful
23 statements about the products they sell, and no law could lawfully restrict that constitutional right.

24 118. Had Defendants provided adequate warnings and instructions and properly disclosed
25 and disseminated the risks associated with their Baby Foods, Plaintiff could have avoided the risk of
26 developing injuries and could have obtained or used alternative products. However, as a result of
27 Defendants' concealment of the dangers posed by their Baby Foods, Plaintiff could not have averted
28 his injuries.

1 119. Defendants' conduct, as described above, was reckless. Defendants risked the lives of
2 consumers and users of their products, including Plaintiff, with knowledge of the safety problems
3 associated with Baby Foods, and suppressed this knowledge from the general public. Defendants
4 made conscious decisions not to redesign, warn or inform the unsuspecting public. Defendants'
5 reckless conduct warrants an award of punitive damages.

6 120. The Defendants' lack of adequate warnings and instructions accompanying their Baby
7 Foods were a substantial factor in causing Plaintiff's injuries.

8 121. As a direct and proximate result of the Defendants' failure to provide an adequate
9 warning of the risks of Baby Foods, Plaintiff has been injured, sustained severe and permanent pain,
10 suffering, disability, impairment, loss of enjoyment of life, economic loss and damages including, but
11 not limited to past and future medical expenses, lost income, and other damages.

12 122. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in
13 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
14 other and further relief as this Court deems just and proper.

15 **COUNT V: NEGLIGENT PRODUCT DESIGN**

16 123. The Defendants knew or, by the exercise of reasonable care, should have known,
17 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby
18 Foods.

19 124. The Defendants owed a duty to all reasonably foreseeable users to design a safe
20 product.

21 125. The Defendants breached their duty by failing to use reasonable care in the design of
22 Baby Foods because the product exposed users to unsafe levels of Toxic Heavy Metals.

23 126. The Defendants breached their duty by failing to use reasonable care in the design of
24 Baby Foods by negligently designing the Baby Foods with ingredients and/or components high in
25 Toxic Heavy Metals.

26 127. The Defendants breached their duty by failing to use reasonable care in the design of
27 Baby Foods by negligently designing and formulation, in one or more of the following ways:

28 When placed in the stream of commerce, Defendants' Baby Foods were defective in design

1 and formulation, and, consequently, dangerous to an extent beyond that which an ordinary consumer
2 would contemplate;

3 When placed in the stream of commerce, Defendants' Baby Foods were unreasonably
4 dangerous in that they were hazardous and posed a grave risk of neurodevelopmental disorders and
5 other serious illnesses when used in a reasonably anticipated manner;

6 When placed in the stream of commerce, Defendants' Baby Foods contained unreasonably
7 dangerous design defects and were not reasonably safe when used in a reasonably anticipated or
8 intended manner;

9 Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically,
10 the content of Toxic Heavy Metals in the ingredients used to manufacture the foods and/or the
11 finished products;

12 Defendants did not sufficiently test, investigate, or study their Baby Foods and, specifically,
13 the ability for Baby Foods to expose babies to high amounts of Toxic Heavy Metals;

14 Exposure to Baby Foods presents a risk of harmful effects that outweigh any potential utility
15 stemming from the use of the products;

16 Defendants knew or should have known at the time of marketing Baby Foods that exposure to
17 Toxic Heavy Metals contained in the Baby Foods could result in brain injury that manifests as ASD
18 and other severe illnesses and injuries;

19 a. Defendants did not conduct adequate post-marketing surveillance of their Baby
20 Foods; and

21 b. Defendants could have employed safer alternative designs and formulations.
22 For example, the Defendants could have avoided use of certain ingredients
23 high in Toxic Heavy Metals, avoided using pre-mix vitamins high in Toxic
24 Heavy Metals, and/or sampled their ingredients from other sources.

25 128. The Defendants breached their duty by failing to use reasonable care by failing to use
26 cost effective, reasonably feasible alternative designs. There was a practical, technically feasible, and
27 safer alternative design that would have prevented the harm without substantially impairing the
28 reasonably anticipated or intended function of Defendants' Baby Foods.

1 129. A reasonable company under the same or similar circumstances would have designed
2 a safer product.

3 130. Plaintiff was harmed directly and proximately by the Defendants' failure to use
4 reasonable care in the design of their Baby Foods. Such harm includes significant exposure to a Toxic
5 Heavy Metals, which can cause or contribute to brain injury that manifests as ASD and related
6 *sequalae*.

7 131. Defendants' defective design of Baby Foods was willful, wanton, malicious, and
8 conducted with reckless disregard for the health and safety of consumers of the Baby Foods,
9 including Plaintiff.

10 132. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's
11 injuries.

12 133. As a direct and proximate result of the Defendants' defective design of the Baby
13 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
14 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past
15 and future medical expenses, lost income, and other damages.

16 134. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in
17 Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such
18 other and further relief as this Court deems just and proper.

19 **COUNT VI: NEGLIGENT MANUFACTURING**

20 135. Plaintiff incorporates by reference each allegation set forth in preceding paragraphs as
21 if fully stated herein.

22 136. At all relevant times, the Defendants manufactured, tested, marketed, sold, and
23 distributed the Baby Foods that Plaintiff consumed.

24 137. The Defendants had a duty to exercise reasonable care, in the manufacturing, testing,
25 marketing, sale, and distribution of Baby Foods.

26 138. The Defendants knew or, by the exercise of reasonable care, should have known, use
27 of Baby Foods were carelessly manufactured, dangerous, harmful and injurious when used by
28 Plaintiff in a reasonably foreseeable manner.

1 139. The Defendants knew or, by the exercise of reasonable care, should have known,
2 ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of Baby
3 Foods improperly manufactured, tested, marketed, distributed, and sold.

4 140. Without limitation, examples of the manner in which Defendants breached their duty
5 to exercise reasonable care in manufacturing Baby Foods, included:

- 6 a. Failure to adequately inspect/test the Baby Foods during the manufacturing
7 process;
- 8 b. Failure to implement procedures that would reduce or eliminate levels of Toxic
9 Heavy Metals in Baby Foods; and
- 10 c. Failure to avoid using ingredients free from, or which contain far less, Toxic
11 Heavy Metals to manufacture Baby Foods.

12 141. A reasonable manufacturer under the same or similar circumstances would have
13 implemented appropriate manufacturing procedures to better ensure the quality and safety of their
14 product.

15 142. Plaintiff was harmed directly and proximately by the Defendants' failure to use
16 reasonable care in the manufacture of their Baby Foods. Such harm includes significant exposure to a
17 Toxic Heavy Metals, which can cause or contribute to brain injury which manifests as ASD and
18 related *sequelae*.

19 143. Defendants' improper manufacturing of Baby Foods was willful, wanton, malicious,
20 and conducted with reckless disregard for the health and safety of users of the Baby Foods, including
21 Plaintiff.

22 144. The defects in Defendants' Baby Foods were substantial factors in causing Plaintiff's
23 injuries.

24 145. As a direct and proximate result of the Defendants' improper manufacturing of Baby
25 Foods, Plaintiff has been injured, sustained severe and permanent pain, suffering, disability,
26 impairment, loss of enjoyment of life, economic loss and damages including, but not limited to past
27 and future medical expenses, lost income, and other damages.

28 146. **WHEREFORE**, Plaintiff respectfully requests this Court to enter judgment in

Plaintiff's favor for damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

JURY TRIAL DEMAND

147. Plaintiff demands a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

148. WHEREFORE, Plaintiff requests the Court to enter judgment in Plaintiff's favor and against the Defendants for:

- a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;
- b. exemplary and punitive damages sufficient to punish and deter the Defendants and others from future wrongful practices;
- c. pre-judgment and post-judgment interest;
- d. costs including reasonable attorneys' fees, court costs, and other litigation expenses;
- and
- e. any other relief the Court may deem just and proper.

Dated: March 21, 2024

CRAIG P. KENNY & ASSOCIATES

/s/ Billie-Marie Morrison

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